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RECORD OF ORAL HEARING
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Appeal 2010-005829
Application 10/590,808
Technology Center 1600

Oral Hearing Held: Wednesday, July 6, 2011

Before TERESA STANEK REA, LORA M. GREEN, and
FRANCISCO C. PRATS, Administrative Patent Judges

ON BEHALF OF THE APPELLANTS:

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The above-entitled matter came on for hearing on Wednesday, July 6, 2011, commencing at 1:55 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, 9th Floor, Alexandria, Virginia, before Kevin E. Carr, Notary Public.

THE CLERK: Good afternoon. This is Calendar No. 2, Appeal No. 2010-005829. Mr. Dan Pereira.

JUDGE REA: Thank you.

Counsel, we're already familiar with the record.

MR. PEREIRA: Okay.

JUDGE REA: So you don't have to go back to the beginning of time. So.

MR. PEREIRA: (Laughing.)

JUDGE REA: Please any time.

MR. PEREIRA: Okay.

Well, and I'll try to keep my comments brief, and then leave the floor open for questions.

So the invention here is a method for treating specific diseases related the vasculature system, and coronary obstruction and peripheral vasoconstriction.

I think at issue here with the Court, an issue that you all need to decide, is whether there would have been a reasonable expectation of treating those specific diseases, based on the prior art's teaching of the same compound in the Liu reference for the treatment of other disorders and specifically in the Examiner's construction of the prior art, diabetes.

And the reason why, obviously, we think we're correct, as opposed to the Examiner, is because the Examiner is focused on certain aspects of that second reference.

And in particular, I would refer to the Sours publication, which is the second rejection of the three in the obviousness rejection here, which provides some discussion that there is a correlation between people who

have diabetes and people who have coronary diseases: High blood pressure, hypertension, things of that nature.

But the Applicant's view, or Appellant's view, I guess in this situation, is that when you read the entire reference, as I believe we all are supposed to do so, that tight connection that the Examiner seems to make in the rejection that if you treat diabetes, you're going to treat, you know, vasoconstriction or peripheral disorders in the circulatory system, that that's not so tight.

There is clear discussion, in the Sours reference, for example, that says, you know, sometimes when we treat -- in one set of studies, when we treat the patients with a certain drug, sometimes we exasperate the condition of diabetes, as opposed to treating it, with drugs such as hypertensive drugs.

Again, this is all in the record. For example, on the first page of the Sours reference, it says, "Hypertensive patients who were taking Beta blockers, had a 28 percent higher risk of diabetes than those taking no medication."

Now that then follows that there were some additional studies, where the showed some benefit with certain types of antihypertensive drugs that did have an effect on diabetes.

Then you have a discussion in Sours, for example, on 1055 through 1056, columns 2 through 1 there, that say, well -- and the focus, again, of most of this review article of Sours, was you know, what types of hypertensive drugs could be used, and how they related for diabetes;

And one of the aspect of this reference that the Examiner has focused on in addition to just the abstract, is this Hope trial, which is discussed starting at 1055.

And what the Examiner takes from that, again, is that, well: If you treat diabetes, you're going to have a reasonable expectation of treating these coronary diseases, or circulatory diseases.

And what this, I think, says is that the ACE inhibitors -- that's the focus of that Hope study -- may involve changed in blood flow, may

involve a cellular mechanism, could affect the secretion of insulin from the pancreas, could be a receptor issue, could be any number of things.

And so what I think the Appellants have continued to argue, both in these responses, the appeal brief, and the Reply Brief, is that when you construct things on paper, and you find this claim -- and I recognize, you know, the dispute in terms of hindsight -- but if you look at this claim, and figure out how you would fit the prior art into that claim, then that's reasonable.

But in the reality of the world and the reality of medical treatments, when you are conducting a set of experiments in human patients, sometimes it will work, maybe sometimes it won't work.

I mean, that's why we have rigorous clinical trials. That's why we have, you know, multi-drug approaches to even a single disease, let alone a patient who has a number of diseases:

He could have blood pressure, kidney disorders, diabetes, obesity. You know, they all have a correlation to each other.

We all know, from just looking at the news or reading the literature, that people who are obese have a higher risk of hypertension and have a higher risk of diabetes, have a higher risk of -- I don't know, I can probably continue on, but that's probably not relevant.

So the point here is that, yes, there is some teaching in the secondary references that there is a correlation between diabetes and hypertension, and thus cardiovascular disorders.

But given the nature of these teachings, the Appellants disagree that there would have been a reasonable expectation for using diabetic drugs to treat cardiovascular conditions, as a general course.

JUDGE GREEN: Now if you give this drug to a diabetic patient, who has hypertension, would you be inherently also treating the hypertension? Since it treats hypertension as well?

MR. PEREIRA: I don't know.

And the reason I don't know, I mean, number one, I'm not a clinician and I've never done any experiments. But more to the point is that --

JUDGE GREEN: I mean, why wouldn't this drug treat hypertension in the diabetic patient, as well as a regular patient?

I mean, your claim covers treatment to anybody with a cardiovascular disease, including a patient with diabetes.

MR. PEREIRA: Yeah. Right. With or without diabetes. The claim does cover that. Correct.

JUDGE GREEN: Right. So if you're treating a diabetic with this drug to treat the diabetes, your claim also would encompass treating the hypertension in that diabetic patient.

MR. PEREIRA: Well, potentially.

JUDGE PRATS: Well, actually, according to your own spec, if somebody is suffering from one of these disorders and gets this drug, you inherently treat it.

Correct?

MR. PEREIRA: Which disorders? I'm sorry.

JUDGE PRATS: Coronary obstruction or peripheral vasoconstriction.

MR. PEREIRA: Right. That is the focus of this application. So if you use that drug and target those patients, that would be the net result.

JUDGE PRATS: And the Examiner is saying: Well, Sowers discloses that a lot of diabetics are going to have these disorders; so therefore, it would be obvious, when you administer this to a diabetic, it's also obvious to administer this to a patient who is going to need treatment for coronary obstruction or peripheral vasoconstriction.

And therefore, you're inherently treating in that diabetic, the disorder that you cite in your claim.

MR. PEREIRA: Yeah. I mean, I guess there's a couple of points there. This is not a case of inherency, I don't think. Because I don't

think the record's been established that all diabetic patients have these coronary diseases.

JUDGE PRATS: No, but it would be those ones.

JUDGE GREEN: Well, you don't have to have all.

MR. PEREIRA: Or -- sorry.

JUDGE PRATS: So, correct. It's obvious to administer to a diabetic. Correct?

MR. PEREIRA: Well, that's what Liu teaches.

JUDGE PRATS: That's what Liu teaches. It's also obvious that diabetics disproportionately suffer from these two diseases that are in your claim, correct?

MR. PEREIRA: I wouldn't say that necessarily the evidence shows it's disproportionately that diabetic patients suffer; it's just a common thing that happens in diabetic patients is these coronary diseases.

JUDGE GREEN: So a large percentage of diabetic patients would be suffering from these diseases?

MR. PEREIRA: Right. But there are probably -- and I don't have numbers at the tip of my fingers -- but there are probably a large number of patients who have cardiac problem or circulatory problems, that have no diabetes whatsoever.

JUDGE PRATS: Correct. But I think what the Examiner is saying is it would be obvious to administer this agent to a diabetic who also suffers from coronary obstruction or peripheral vasoconstriction;

And therefore, once you administer it to that patient, you inherently get the effect that's described in your specification.

And I think that's a pretty good argument.

MR. PEREIRA: Well, I mean, I'd have to go back to where I started, with that we just don't think there is a reasonable expectation of success, based on the record of the references;

Because you know, what Sowers and the other reference, Parissis, teaches, is the correlative aspects of that argument.

Liu provides a one-paragraph notation that says: Well, you can use these for any number of diseases: Diabetes, inflammatory, washing your car.

I'm sorry, that's a joke.

JUDGE GREEN: But I'm just not seeing --

MR. PEREIRA: It's that, you know, you can construct a treatment regimen on paper; but we don't believe that in the context of one of ordinary skill in the art, that they would have recognize that they would have a reasonable expectation of success in using Liu's compounds for the treatment of generally different types of disorders.

JUDGE GREEN: Well, see, that's where I don't understand where the reasonable expectation of success comes in; because you're treating a diabetic patient with this drug. I mean, that's the primary reference, Liu.

MR. PEREIRA: Right.

JUDGE GREEN: And Sowers --

MR. PEREIRA: Well, there is a suggestion for that, correct.

JUDGE GREEN: Sours teaches that there is a correlation between diabetes and cardiovascular diseases --

MR. PEREIRA: Right --

JUDGE GREEN: A large part of that.

So once you start treating the diabetic, aren't you going to be inherently treating this amount, these other diseases that your specification teaches?

Unless there's something on the record that you have different amounts, if you treat a diabetic with different amounts than you treat cardiovascular diseases, or something else.

MR. PEREIRA: Right. Yeah.

JUDGE GREEN: I didn't see any argument like that, but maybe there's something in the record.

MR. PEREIRA: Right.

No, yeah, there is no record as of today, for sure, that indicates that there is, you know, different dose intervention, or what not, addressing the latter point of your comment.

But coming back to the aspect, well, if you use the compounds to treat diabetes, that you wouldn't necessarily presume to expect that you could also treat these other disorders;

And I think that's where the disagreement on the Sowers reference comes in, is because Sowers says: Well, sometimes you use hypertensive drugs, or sometimes you use certain types of drugs. And they have no effect, and sometimes they do the opposite to what you would have expected;

That is, that if the commonality or the link between hypertension and diabetes is as reasonably as it would seem, then in all indications where you use a drug for treating hypertension or you use a drug for treating diabetes, then the expectation would be that you would have an overall positive effect.

And I think that the evidence within the Sowers reference, I mean, there is no extraneous evidence, no other documents that the Appellants have cited that lends them to believe that there just isn't a reasonable expectation of success for using that type of drug in a regimen for treating cardiovascular diseases.

JUDGE GREEN: Well, I guess with the inherency argument, though, you don't have to recognize the property. You don't have to recognize the property of that compound; because I mean, that's the whole point behind inherency is that you can have both recognized and unrecognized properties of that compound.

MR. PEREIRA: Sure.

JUDGE GREEN: So the fact that the reference didn't recognize that it's also teaching cardiovascular disease, you're still treating the same or overlapping patient populations with the same drug; and we're just trying to see how your claim would fall outside of that.

JUDGE REA: Counsel, I think you're arguing your claim narrower than how it now reads. So you're focusing on the non-diabetic population.

But the diabetic, when administered these methylene amides, are being given that medication because they're diabetics.

Diabetics have difficulty with their circulatory system. It makes sense that the circulation of their heart may be affected by their disease state, and they would get some benefit from it.

MR. PEREIRA: Yes.

Anyway, to answer the -- I do recognize that the claim -- and I think we conceded that in the initial appeal brief -- that the claim covers, you know, whether or not the patient has diabetes, I mean, that the scope of the claim does encompass both diabetic patients and non-diabetic patients.

You know, I mean, the aspect of inherency, I don't know if it was being applied on a 102 Anticipation Rejection; I think the argument would be, quite simply, that there is evidence in the record that not all diabetic patients have cardiovascular diseases;

And so there are distinct different populations; although there are potentially -- and there is, from the record -- a point of overlap.

But still, even if you administer to the diabetic patient, I think what Sours is describing -- if you read the reference in its entirety -- is that if you treat diabetes, you are not necessarily going to be treating cardiovascular disorders.

Because, for example, yes diabetes and insulin resistance or any of the associated --

JUDGE REA: Because it's a different dosage form?

MR. PEREIRA: But it's a different disease. They have different -- you know, there are commonalities, in terms of there can be, for example, where I was going with this is, is that:

Diabetes can be, you know, a causative agent for cardiovascular diseases; and cardiovascular diseases, perhaps, can also be a causative agent for diabetes.

However, there are a number of different factors that go into whether or not cardiovascular diseases, as a matter of course, will develop. And that could be genetic predispositions, environmental conditions, and other cellular enzymatic mechanisms that are unrelated to diabetes.

And what they're saying is that: Just because you have two conditions in a single patient, that have some correlation, that there isn't necessarily an nexus between those;

And our view of Sours is that you wouldn't have a reasonable expectation that if you would treat diabetes, you would also have an expectation of treating the other conditions;

Because in some instances, when they use hypertensive drugs, there were negative effects, that is, increased incidences of diabetes. And Sours itself says this mechanism may have nothing to do with blood flow or the cardiovascular system may rely on some cellular enzymatic mechanism.

And if you're targeting, for example, in using some of the drugs in the Sours reference, that if you're targeting a cellular enzymatic mechanism, specifically related to the pancreas, let's say, or some hormonal release from the brain, that affects insulin secretion from the pancreas, that is probably not going to have a reasonable effect on the cardiovascular condition.

I mean, believe me, I understand all of your points, in terms of the inherency and the administration to the diabetes.

But what I think the nature of the references are, is that that isn't clear-cut; it's very cloudy, as to terms of what will happen, could happen, when you use a drug that, you know, has never been specifically taught or discussed as being useful for treating those types of cardiovascular conditions.

JUDGE REA: I don't have --

JUDGE PRATS: The only teaching we have as to who should receive these drugs is Liu. Right?

MR. PEREIRA: Yes.

JUDGE PRATS: And so the list is the types of diabetes, obesity, autoimmune, inflammation, osteoporosis, and some cancer.

Now the Examiner also sort of suggested that obesity might come under the patient population that would need treatment for the claim disorders.

Is there any evidence to support that?

MR. PEREIRA: Support which?

JUDGE PRATS: Support that obesity is somehow linked to cardiovascular obstruction, or peripheral vasoconstriction?

Because the Examiner has kind of intimated that, when he argues --

MR. PEREIRA: Yeah. I don't recall specifically whether there has been, you know -- I've been focusing more on the diabetic angle, of course.

But I mean, I probably have to say that, you know, I know from just the general news and you know, the scientific literature, that obese people do have a higher propensity to have cardiovascular conditions, as a result of their, you know, increased weight and particularly also the strain that that provides to the heart, when having to pump blood through, you know, that type of system.

Typically also you end up -- people who are obese have higher cholesterol levels, have higher fatty deposits, and arteries, which will also then cause vasoconstriction, as well.

Again, that's sort of generalized, but the evidence of record has been established, I think, in that regard.

JUDGE PRATS: Thank you.

JUDGE REA: We have nothing further.

MR. PEREIRA: All right. Well, thank you very much. Enjoy the rest of your afternoon.

JUDGE PRATS: Thanks very much.

JUDGE REA: Thank you.

(Whereupon, at 2:10 p.m., the proceedings were concluded.)

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